K091190

**ZIMMER SPINE**
**SUMMARY OF SAFETY AND EFFECTIVENESS**

| | |
|---|---|
| **SUBMITTER:** | Zimmer Spine |
| | JUL 30 2009 |
| **MANUFACTURER ESTABLISHMENT REGISTRATION NUMBER:** | 3003853072 |
| **CONTACT PERSON:** | David Padgett, RAC (US)<br>Senior Specialist, Regulatory Affairs<br>Telephone: (512) 533-1998<br>Fax: (512) 258-0995 |
| **DATE:** | June 30, 2009 |
| **TRADE NAME:** | Universal Clamp® Stainless Steel System |
| **PRODUCT CODE:** | JDQ |
| **CLASSIFICATION NAME:** | Bone Fixation Cerclage |
| **CLASSIFICATION REFERENCE:** | 21 CFR § 888.3010 |
| **PREDICATE DEVICE:** | Abbott Spine Universal Clamp Stainless Steel System |
| **DEVICE DESCRIPTION:** | The Universal Clamp Stainless Steel System is a temporary orthopedic implant intended to provide stabilization during the development of solid bony fusion and aid in the repair of bone fractures. The device system is designed to be incorporated into constructs and used in conjunction with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants. |
| **INDICATIONS:** | The Universal Clamp Stainless Steel System is a temporary orthopedic implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:<br><br>1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques.<br>2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis.<br>3. Spinal degenerative surgery, as an adjunct to spinal fusions;<br><br>The Universal Clamp Stainless Steel System may also be used in conjunction with other medical implants made |

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of stainless steel whenever "wiring" may help secure the attachment of other implants.

**COMPARISON TO PREDICATE DEVICE:**

Engineering evaluations and bench testing were conducted to assess the physical and mechanical properties of the subject device. These results demonstrate that the performance of the Abbott Spine Universal Clamp® Stainless Steel System is substantially equivalent to the predicate stainless steel version cleared under premarket notification K081622.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Zimmer Spine
% Mr. David Padgett, RAC
Senior Specialist, Regulatory Affairs
5301 Riata Park Court, Building F
Austin, TX, 78727

Re: K091190
Trade/Device Name: Clamp® Stainless Steel System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: June 30, 2009
Received: July 2, 2009

Dear Mr. Padgett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

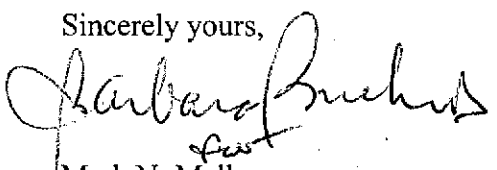
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K091190

**Device Name:**

Universal Clamp® Stainless Steel System

**Indications for Use:**

The Universal Clamp Stainless Steel System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone factures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions;

The Universal Clamp Stainless Steel System may also be used in conjunction with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for Mum) (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091190